

IN THE CLAIMS

The status of each claim is provided below.

Claims 1-43: Canceled.

44. (New) $7\alpha,11\beta$ -dimethyl- 17β -[[$(\text{trans-4-(n-butyl)cyclohexyl)carbonyl}$]oxy]estr-4-en-3-one.

45. (New) A pharmaceutical composition, comprising:

- a) a pharmaceutically effective amount of $7\alpha,11\beta$ -dimethyl- 17β -[[$(\text{trans-4-(n-butyl)cyclohexyl)carbonyl}$]oxy]estr-4-en-3-one; and
- b) a pharmaceutically acceptable carrier.

46. (New) The pharmaceutical composition of Claim 45, which is suitable for injection.

47. (New) A method of effecting hormonal treatment in a mammal which comprises administering an effective amount of $7\alpha,11\beta$ -dimethyl- 17β -[[$(\text{trans-4-(n-butyl)cyclohexyl)carbonyl}$]oxy]estr-4-en-3-one to a mammal in need thereof.

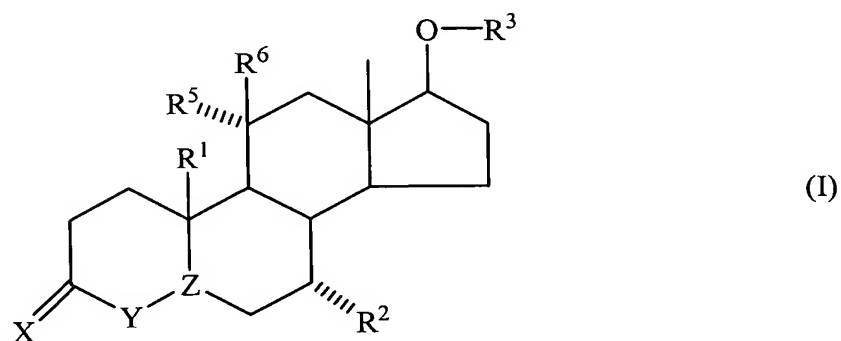
48. (New) The method of Claim 47, wherein the mammal is a male.

49. (New) The method of Claim 47, wherein the mammal is a male and the hormonal treatment is controlling male fertility.

50. (New) The method of Claim 47, further comprising administering a progestin.

51. (New) The method of Claim 47, wherein the method is treating muscle maintenance.

52. (New) A compound of the formula (I):



wherein

R^1 is H or lower alkyl;

Y-Z is CH=;

R^2 is an α -substituent which is unsubstituted lower alkyl;

R^3 is (CO)- R^4 , wherein R^4 is C_{10} alkyl;

R^5 is α -H, and R^6 is β -lower alkyl; and

X is O.

53. (New) The compound of Claim 52, wherein

R^1 is H;

R^2 is methyl; and

R^6 is methyl.

54. (New) A pharmaceutical composition, comprising:

- a) the compound of Claim 52; and
- b) a pharmaceutically acceptable carrier.

55. (New) A pharmaceutical composition, comprising:

- a) the compound of Claim 53; and
- b) a pharmaceutically acceptable carrier.

56. (New) The pharmaceutical composition of Claim 54, which is suitable for injection.

57. (New) The pharmaceutical composition of Claim 55, which is suitable for injection.

58. (New) A method of effecting hormonal treatment in a mammal which comprises administering an effective amount of the compound of Claim 52 to a mammal in need thereof.

59. (New) A method of effecting hormonal treatment in a mammal which comprises administering an effective amount of the compound of Claim 53 to a mammal in need thereof.

60. (New) The method of Claim 58, wherein the mammal is a male.

61. (New) The method of Claim 59, wherein the mammal is a male.

62. (New) The method of Claim 58, wherein the mammal is a male and the hormonal treatment is controlling male fertility.

63. (New) The method of Claim 59, wherein the mammal is a male and the hormonal treatment is controlling male fertility.

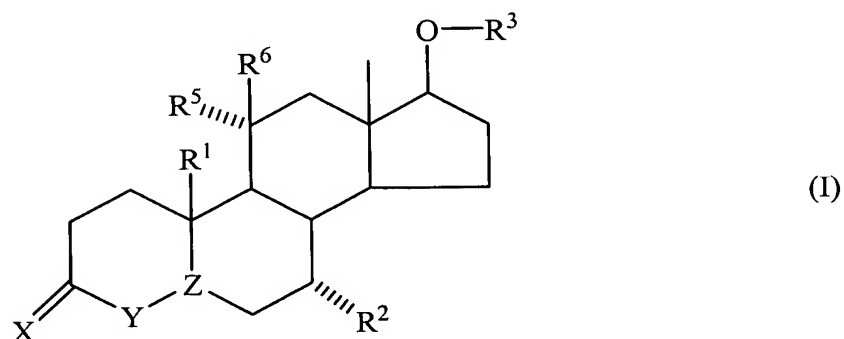
64. (New) The method of Claim 58, further comprising administering a progestin.

65. (New) The method of Claim 59, further comprising administering a progestin.

66. (New) The method of Claim 58, wherein the method is treating muscle maintenance.

67. (New) The method of Claim 59, wherein the method is treating muscle maintenance.

68. (New) A method of making a compound of the formula (I):



wherein

R^1 is H or lower alkyl;

Y-Z is CH= or CH₂-CH, wherein H is α to the rings; or Y-CH, wherein H is α to the rings and Y is S, O, or NR¹⁰, wherein R¹⁰ is H or lower alkyl;

R² is an α -substituent which is unsubstituted lower alkyl or fluoro-substituted lower alkyl;

R³ is C₁-C₈ alkyl, or C₂-C₈ alkenyl or alkynyl which are optionally substituted; or R³ is C₄-C₈ cycloalkyl which is unsubstituted or substituted; or R³ is C₆-C₁₈ aryl which is unsubstituted or substituted; or R³ is a 5- to 15-membered heterocycle which is unsubstituted or substituted, and further wherein any of the above may be further substituted with 1 to 3 heteroatoms or 1 to 5 halogen atoms or both; or

R³ is H or acyl group (CO)-R⁴, wherein R⁴ is C₁-C₁₈ alkyl, or C₂-C₁₈ alkenyl or C₂-C₁₈ alkynyl which are optionally substituted; or R⁴ is C₄-C₁₈ cycloalkyl or substituted cycloalkyl; or R⁴ is C₆-C₁₈ aryl or substituted aryl; or R⁴ is a 5- to 15-membered heterocycle or substituted heterocycle, and wherein R⁴ may be optionally substituted with 1 to 3 heteroatoms or 1 to 5 halogen atoms or both;

R⁵ is α -H, and R⁶ is β -lower alkyl, alkenyl or alkynyl which are optionally substituted, or R⁵R⁶ is =CH₂; and

X is O, H₂, (H, OH) or (H, OCOR⁴), wherein R⁴ is as defined above; or X is (H, OR³), wherein R³ is as defined above; or X is NOR⁷, wherein R⁷ is H or C₁-C₈ alkyl, or C₂-C₈ alkenyl or alkynyl which are optionally substituted; or R⁷ is C₄-C₈ cycloalkyl which is unsubstituted or substituted; or R⁷ is C₆-C₁₈ aryl or substituted aryl; or R⁷ is a 5- to 15-membered heterocycle which is unsubstituted or substituted, and R⁷ may be optionally substituted with 1 to 3 heteroatoms or 1 to 5 halogen atoms or both; or X is (OR⁸, OR⁹), where R⁸ and R⁹ are lower alkyl, or (OR⁸, OR⁹) is a cyclic structure containing 2 to 3 carbon atoms, optionally substituted with lower alkyl, or 1 or 2 heteroatoms or halogens;

which comprises:

- a) introducing a 6,7-double bond into adrenosterone;
- b) effecting 1,6-addition of a methyl group by reaction with an organometallic reagent, followed by acid treatment;
- c) introducing a 1,2-double bond;
- d) protecting the 17-ketone functionality;
- e) reducing the 11-ketone group to an 11-hydroxy group;
- f) aromatizing the A-ring to a phenol;
- g) alkylating the phenol ring to an alkoxy arene compound;
- h) oxidizing the 11-hydroxyl to an 11-ketone;
- i) converting the 11-ketone to 11-methylene;
- j) removing the protecting group at C-17 to yield the ketone;
- k) reducing the 11-methylene to 11 β -methyl;
- l) reducing the 17-ketone to 17 β -hydroxyl; and
- m) converting the 3-alkoxy arene to a 4-en-3-one compound.

Claim 69 (New): The method of Claim 68, wherein step a) is effected by an electronegatively-substituted quinone.

Claim 70 (New): The method of Claim 68, wherein step b) is effected by a methyllithium copper complex.

Claim 71 (New): The method of Claim 68, wherein step c) is effected by an electronegatively-substituted quinone.

Claim 72 (New): The method of Claim 68, wherein step d) is effected by ketal formation with a 1,2- or 1,3-diol.

Claim 73 (New): The method of Claim 68, wherein step e) is effected by a complex metal hydride reagent.

Claim 74 (New): The method of Claim 68, wherein step f) is effected by a metal/arene mixture.

Claim 75 (New): The method of Claim 68, wherein step g) is effected by either an alkyl halide or an activated alkyl ester in the presence of a base.

Claim 76 (New): The method of Claim 68, wherein step h) is effected by a chromium oxidant.

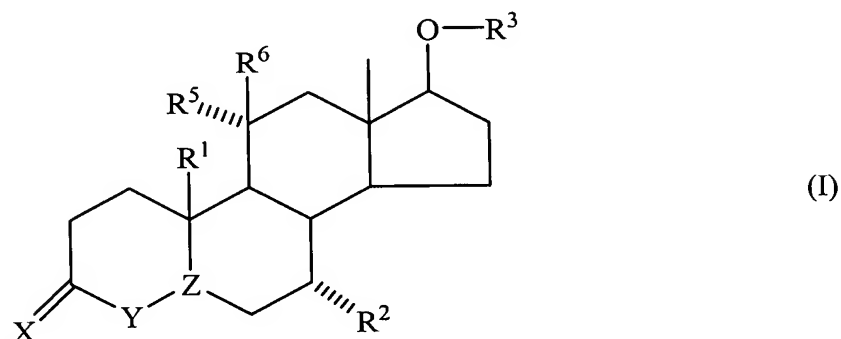
Claim 77 (New): The method of Claim 68, wherein step i) and j) are effected by a trialkyl silylmethyl organometallic reagent followed by treatment with an acid.

Claim 78 (New): The method of Claim 68, wherein step k) is effected by metal-catalyzed hydrogenation.

Claim 79 (New): The method of Claim 68, wherein step l) is effected by a complex metal hydride reagent.

Claim 80 (New): The method of Claim 68, wherein step m) is effected by a dissolving metal in an amine solvent followed by acid treatment.

Claim 81 (New) A method of making a compound of the formula (I):



wherein

R^1 is H or lower alkyl;

Y-Z is CH= or CH₂-CH, wherein H is α to the rings; or Y-CH, wherein H is α to the rings and Y is S, O, or NR¹⁰, wherein R¹⁰ is H or lower alkyl;

R^2 is an α -substituent which is unsubstituted lower alkyl or fluoro-substituted lower alkyl;

R^3 is C₁-C₈ alkyl, or C₂-C₈ alkenyl or alkynyl which are optionally substituted; or R^3 is C₄-C₈ cycloalkyl which is unsubstituted or substituted; or R^3 is C₆-C₁₈ aryl which is unsubstituted or substituted; or R^3 is a 5- to 15-membered heterocycle which is unsubstituted or substituted, and further wherein any of the above may be further substituted with 1 to 3 heteroatoms or 1 to 5 halogen atoms or both; or

R^3 is H or acyl group (CO)- R^4 , wherein R^4 is C₁-C₁₈ alkyl, or C₂-C₁₈ alkenyl or C₂-C₁₈ alkynyl which are optionally substituted; or R^4 is C₄-C₁₈ cycloalkyl or substituted cycloalkyl; or R^4 is C₆-C₁₈ aryl or substituted aryl; or R^4 is a 5- to 15-membered heterocycle or

substituted heterocycle, and wherein R^4 may be optionally substituted with 1 to 3 heteroatoms or 1 to 5 halogen atoms or both;

R^5 is α -H, and R^6 is β -lower alkyl, alkenyl or alkynyl which are optionally substituted, or R^5R^6 is $=CH_2$; and

X is O, H_2 , (H, OH) or (H, $OCOR^4$), wherein R^4 is as defined above; or X is (H, OR^3), wherein R^3 is as defined above; or X is NOR^7 , wherein R^7 is H or C_1 - C_8 alkyl, or C_2 - C_8 alkenyl or alkynyl which are optionally substituted; or R^7 is C_4 - C_8 cycloalkyl which is unsubstituted or substituted; or R^7 is C_6 - C_{18} aryl or substituted aryl; or R^7 is a 5- to 15-membered heterocycle which is unsubstituted or substituted, and R^7 may be optionally substituted with 1 to 3 heteroatoms or 1 to 5 halogen atoms or both; or X is (OR^8 , OR^9), where R^8 and R^9 are lower alkyl, or (OR^8 , OR^9) is a cyclic structure containing 2 to 3 carbon atoms, optionally substituted with lower alkyl, or 1 or 2 heteroatoms or halogens,

which consists essentially of introducing the 7α -substituent prior to introducing the 11β -substituent.

Claim 82 (New): A method of making $7\alpha,11\beta$ -dimethyl- 17β -[[$(trans$ -4-(n-butyl)cyclohexyl)carbonyl]oxy]estr-4-en-3-one, which consists essentially of introducing the 7α -methyl substituent prior to introducing the 11β -methyl substituent.

Claim 83 (New): A method of making the compound of Claim 52, which consists essentially of introducing the 7α -substituent prior to introducing the 11β -substituent.

Claim 84 (New): A method of making the compound of Claim 53, which consists essentially of introducing the 7α -methyl substituent prior to introducing the 11β -methyl substituent.

SUPPORT FOR THE AMENDMENTS

The specification has been amended to insert continuing application data. Newly-added Claims 44-84 are supported by the specification at pages 2-35 and original Claims 1-43. In Claim 52, the definition of R⁴ as C₁₀ alkyl is supported by the specification at page 3, line 11. The range of C₁-C₁₈ alkyl provides descriptive support for C₁₀ alkyl.

No new matter is believed to have been added to this application by the amendments submitted above.